IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA		
v.		**No. 3:15-cr-00496-L**
USPLABS, LLC	**(1)**	
JACOBO GEISSLER	**(2)**	
JONATHAN DOYLE	**(3)**	
MATTHEW HEBERT	**(4)**	
KENNETH MILES	**(5)**	
S.K. LABORATORIES, INC.	**(6)**	
SITESH PATEL	**(7)**	
CYRIL WILLSON	**(8)**	

DEFENDANTS' MOTION AND BRIEF TO COMPEL CERTAIN EXPERT MATERIAL

Defendants USPlabs, LLC ("USPlabs"), Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc., Sitesh Patel and Cyril Willson (collectively, the "Defendants"), by and through undersigned counsel, respectfully file this Joint Motion To Compel Expert Material, and would show the Court, as follows:

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I. INTRODUCTION

On June 28, 2017, after the Government's disclosure of its proposed experts under Rule 16 and its production of some limited expert discovery, Defendants requested additional documents that are within the possession, custody, or control of the Government and that are material to Defendants' defense, and in particular the Court's upcoming (though not yet scheduled) hearing on the parties' *Daubert* motions ("Hearing"). Ex. 1 ("June 28 Request"). These documents include basic information such as the expert's workpapers, communications with alleged victims and with each other, as well as documents specific to each expert. The Government, however, has refused to produce those documents "at this time." Ex. 2 ("Gov't's July 5 Reply"). Defendants request that this Court compel the Government to produce the documents requested by Defendants at least 60 days prior to the date of the Hearing, pursuant to Fed. R. Crim. P. 16, and for the reasons stated herein.

II. FACTUAL BACKGROUND

A. The Parties' Agreed-Upon Schedule for Resolution of Expert Issues

The charges in the Superseding Indictment raise a number of highly technical scientific questions requiring expert testimony, including, *inter alia* (1) whether OxyElite Pro New Formula ("OEP NF") (or any of its ingredients) presents a "significant or unreasonable" risk of liver injury (Count 10), and (2) whether 1,3-dimethylamine ("DMAA") occurs naturally in geraniums (Counts 1-5, 7, and 11).[1] First Superseding Indictment, Dkt # 95 ("Indictment").

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[1] Specifically, upon Defendants' proof that DMAA occurs naturally in geraniums, Defendants will establish that DMAA is a legal dietary ingredient (even in synthetic form), and therefore will be able to establish that (1) they did not intend to mislead its customers into selling or consuming an illegal dietary supplement (Counts 1-4), (2) any representations Defendants made to USPlabs customers regarding the actual sourcing of DMAA were immaterial (given its legality even in synthetic form) (Counts 1-4), (3) any purported mislabeling of DMAA as geranium was immaterial (given DMAA's legality) (Count 7), and (4) there was no underlying criminal violation supporting the money laundering conspiracy charge (Count 11).

In light of the complexity of these issues, their centrality to this case, and the need to address them "in an orderly manner well in advance of trial," the parties agreed to a schedule for the disclosure of expert testimony and the filing of *Daubert* motions well in advance of the trial . Jt. Mot. To Modify Scheduling Order, Dkt # 188. The Court referred the parties' respective *Daubert* motions, which challenge each of the Government's 9 proposed experts and Defendants' 12 proposed experts, to Magistrate Judge Toliver on August 9, 2017 (Dkt # 343).

B. The Government's Proposed Experts

The Government's proposed experts are expected to provide testimony relating to 7 of the 11 Counts alleged in the Indictment: (1) Count 10, the adulteration count; (2) Counts 1-5, the wire fraud counts; and (3) Count 11, the money laundering count. *See* Gov't's Notice of Expert Test., Dkt. # 222 ("Gov't Notice"); Indictment. These proposed experts are:

- **Dr. Herbert L. Bonkovsky**. Dr. Bonkovsky is a gastroenterologist, with a sub-specialty in hepatology. Gov't Notice at 2. Dr. Bonkovsky is expected to testify about (1) the alleged link between OEP NF (the dietary supplement at issue in Count 10) and certain liver injuries reported in Hawai'i and elsewhere, (2) the research by Dr. Rolf Teschke, who found that OEP NF was not the likely cause of the cluster of liver injuries reported in Hawaii, and (3) his review of certain medical records. *Id.* at 2-12. One court has already excluded Dr. Bonkovsky's expert testimony in a different litigation,[2] and he has also been retained by some plaintiffs who have brought lawsuits against some of the Defendants.

- **Dr. Karl Klontz**. Dr. Klontz is an FDA-employed epidemiologist. Gov't Notice at 49. He is expected to testify about (1) the role of adverse event reporting in relation to the reported injuries purportedly caused by OEP NF, (2) prior outbreaks of hepatitis linked to other products, their purported resemblance to the outbreak at issue in this case, and about how rare, idiosyncratic instances of liver disease may occur with delayed onset from ingestion, and (3) his conclusion that OEP NF is "most likely responsible for" liver disease among 55 patients described in a paper linking OEP to liver disease. *Id.* at 49-56.

- **Professors Bill Gurley, Igor Koturbash, and Marjan Boerma (the "Gurley Team")**. Professors Gurley, Koturbash, and Boerma are professors at

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[2] *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 410 (S.D.N.Y. 2005); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 549 (S.D.N.Y. 2004).

the University of Arkansas. Gov't Notice at 20. The professors are expected to testify about (1) the safety of multi-ingredient, caffeine-containing dietary supplements, (2) the alleged toxicity of OEP NF, (3) USPlabs' assessment of the safety of OEP NF, and (4) mouse testing involving OEP NF they conducted using an inappropriate, unvalidated, and unreliable methodology. *Id.* at 20-42. Dr. Gurley was designated as an expert in federal court (but not permitted to testify) at least once before.[3]

- **Dr. Mahmoud ElSohly**. Dr. ElSohly is a research professor and professor of "pharmaceutics" at the University of Mississippi. Gov't Notice at 14. Dr. ElSohly has testified numerous times in federal court.[4] He is expected to testify generally about the field of natural products analytical chemistry, the use of detection limits in analytical chemistry research, the synthesis of plant constituents and the concept of enantiomeric ratios in plant constituents, his conclusion that DMAA is not a natural constituent of the geranium plant, and his research on three unrelated OEP NF ingredients, *id.* at 15-19.

- **Nicholas Oberlies.** Professor Oberlies is a Professor of Chemistry & Biochemistry at the University of North Carolina at Greensboro. Gov't Notice at 57. He is expected to testify about (1) the chirality of DMAA and the compositional differences between naturally-sourced and synthetic DMAA, (2) the chemical compositions of aegeline, yohimbe, and cynanchum auriculatum, and (3) his opinion of what constitutes sufficient testing for dietary supplements. *Id.* at 60-74.

- **Catherine D. Tucker**. Catherine Tucker is a consultant and financial investigator. Gov't Notice at 75. Ms. Tucker is expected to testify about the law enforcement tools used to identify financial accounts and to trace financial activity, her experience in this area, and Defendants' movement of money into various bank accounts. *Id.* at 77; Gov't Resp. To Defs.' Mot. To Preclude Expert Test. By Cathy Tucker at 6, Dkt # 284 (Gov't Tucker Resp.").[5]

Defendants have moved to exclude each expert's testimony on a number of grounds, including the unreliability of their methodology, analysis and conclusions, the irrelevance of

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[3] *See In re Ephedra Prod. Liab. Litig.*, No. 04 M.D. 1598 (JCR), 04 CIV. 8556, 2006 WL 2850213, at *2 (S.D.N.Y. Oct. 3, 2006) (striking Dr. Gurley's report in its entirety).

[4] *See, e.g.*, *United States v. Osburn*, 955 F.2d 1500, 1502 (11th Cir. 1992); *Sparling v. Doyle*, No. EP-13-CV-323-DCG, 2015 WL 4528759, at *1 (W.D. Tex. July 27, 2015).

[5] In response to Defendants' Motion to Exclude Ms. Tucker's Testimony, the Government conceded that Ms. Tucker does not have the information required to testify that Defendants intended to conceal money, or even whether the listed entities were legitimate, and agreed that she would not testify regarding Defendants' intent or the legitimacy of other entities or insurance. Gov't Tucker Resp. at 3-4.

certain of their testimony, and certain experts' lack of qualifications.[6] Each of those motions is currently pending.

C. Expert Disclosure And Discovery To Date

On May 1, 2017, the Government produced 4,774 documents relating to its proposed experts, including documents from the University of Mississippi's National Center for Natural Products Research, where Dr. ElSohly is employed and conducted the research relevant to this case. *See* Ex. 3 (May 1, 2017 Runkle letter). Despite this production, however, the Government has failed to produce numerous documents relating to the Government's proposed experts that are material to Defendants' defense and central to a *Daubert* hearing addressing their reliability.

Specifically, the Government has failed to produce the following documents:[7]

- **All Government experts**: Each expert's engagement agreement with the Government, compensation from the Government, prior reports and testimony, workpapers, communications with alleged victims of OEP NF, and communications with each other;

- **Bonkovsky**: Communications between Dr. Bonkovsky and others relating to his opinions in this case, including (1) members of the Drug-Induced Liver Injury Network ("DILIN"); (2) the University of Mississippi, including Drs. Ikhlas Khan and ElSohly; and (3) Phytochemical Sciences, Inc.

- **Klontz**: Documents relating to (1) Klontz's publication or attempted publication of studies of USPlabs' dietary supplements; (2) Klontz's review of patient medical records relating to OEP NF; (3) Klontz's communications with various publications, Paul Howard, the Drug-Induced Liver Injury Network, the Centers for Disease Control, Department of Defense, or various universities

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[6] *See* Defs.' Mot. To Exclude Dr. Herbert Bonkovsky's Test. And Br. In Supp., Dkt # 254-2; Defs. USPLabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc., Sitesh Patel, And Cyril Willson's Mot. To Exclude The Test. Of Dr. Karl Klontz, M.D. And Br. In Supp., Dkt # 255-1; Defs.' Mot. To Exclude Expert Test. By Drs. Gurley, Koturbash, And Boerma And Br. In Supp., Dkt # 253; Defs.' Joint Mot. To Exclude The Expert Test. Of Dr. Mahmoud ElSohly And Br. In Supp., Dkt # 256 ("ElSohly Mot."); Defs.' Mot. To Exclude Expert Test. By Nicholas Oberlies, Ph.D. And Br. In Supp., Dkt # 252; Defs.' Mot. To Exclude Expert Test. By Catherine D. Tucker And Br. In Supp., Dkt # 251.

[7] For more detail on each category of documents, see Ex. 1 (June 28, Request).

- **Gurley, Koturbash, and Boerma**: Documents relating to (1) the mice used in the professors' OEP NF studies; (2) the extractions fed to the mice in those studies; (3) the data documented during those studies; and (4) literature consulted during those studies, or subsequently publishing the results of those studies.

- **ElSohly**: Documents relating to the samples the University of Mississippi tested (either for Dr. ElSohly's studies of OEP NF or for the University of Arkansas's) and communications with (1) his staff; (2) Dr. Danial Armstrong or Ying Zhang regarding DMAA or OEP NF; and (3) Dr. Yi Jin, Xu Xishuangbanna, Jinghua Yang, Wei-Dong Zhang, Juan Su, Dean Guo, or Min Yang relating to the geranium he tested.

- **Oberlies**: Documents relating to or reflecting his studies or the literature he consulted for his opinions regarding chirality of the ingredients identified in his expert report.

- **Tucker**: Ms. Tucker's workpapers underlying her analysis.

Defendants wrote to Government counsel requesting these categories of documents under Fed. R. Crim. P. 16(a)(1)(E)-(G). *See* Ex. 1 (June 28 Request). On July 5, 2017, the Government replied, noting that it would "contact the experts with [Defendants' request]" but otherwise refusing to produce the requested material. Ex. 2 (Gov't's July 5 Reply) (contending that its "expert disclosures under Rule 16(a)(1)(G) were complete," and "declin[ing] [Defendants'] request to engage in additional expert discovery at this time"). To date, the Government has yet to produce the documents identified in Defendants' June 28 request, all of which are material to Defendants' defense and therefore discoverable under Rule 16(a)(1)(E). For the reasons discussed below, the Court should require the Government to produce the requested documents no later than 60 days in advance of the to-be-scheduled *Daubert* hearing, to allow the Court to assess the admissibility of each of the Government's experts on a complete factual record.

III. ARGUMENTS AND AUTHORITIES

Under Rule 16(a)(1)(E), the Government must produce documents and other items that are "within [its] possession, custody, or control" if those documents are "material to preparing [Defendants'] defense." Fed. R. Crim. P. 16(a)(1)(E). Because the expert documents requested by Defendants are (A) material to Defendants' defense and (B) within the Government's possession, custody, or control, they must be produced. Moreover, because they are critical to a pre-trial assessment of the reliability of the testimony of the Government's proposed experts, they must be produced well in advance of the *Daubert* hearing. *See United States v. Diakhoumpa*, 171 F. Supp. 3d 148, 151 (S.D.N.Y. 2016); Fed. R. Evid. 705 advisory committee's notes (1993 amendment).

A. Defendants Are Entitled To The Requested Documents Because They Are Material To Preparing Their Defense.

The documents requested by Defendants are material to their defense. Materiality under Rule 16 requires only "some indication that the pretrial disclosure of the disputed evidence would have enabled the defendant significantly to alter the quantum of proof in his favor." *United States v. Reeves*, 892 F.2d 1223, 1226 (5th Cir. 1990). This standard is "not a heavy burden": "evidence is material under Rule 16 as long as there is a strong indication that it will play an important role in uncovering admissible evidence, aiding witness preparation, corroborating testimony, or assisting impeachment or rebuttal." *United States v. Holy Land Found. for Relief & Dev.*, No. 3:04-CR-240-G, 2007 WL 1308383, at *2 (N.D. Tex. May 4, 2007), *modified*, No. 3:04-CR-240-G, 2007 WL 1599135 (N.D. Tex. June 4, 2007). Both the (1) general expert documents, and (2) expert-specific documents meet this materiality standard.

1. The Requested General Expert Documents Are Material To Preparing Defendants' Defense.

Documentation relating to payment and other terms of engagement, and communications between experts and other witnesses are material and should be produced.

First, documents relating to payment and other terms of engagement are material because they may be used to rebut the Government's expert testimony by showing evidence of bias, and will thus assist in the cross-examination – and thus Defendants' challenge to the admissibility of – the Government's proposed experts. *See, e.g.*, *D'Souza v. Marmaxx Operating Corp.*, EP–15–CV–00256–DCG, 2017 WL 1322243, at *9 (W.D. Tex. Apr. 7, 2017); Fed. R. Civ. P. 26 advisory committee's notes to 2010 amendment).

Second, documents relating to communications between the Government's experts and other witnesses are also material to Defendants' defense. Communications that the proposed experts – especially Drs. Bonkovsky and Klontz – may have had with patients or patients' legal representatives would provide important evidence relating to the quantity and quality of evidence upon which these proposed experts have based their opinions, and may uncover admissible evidence relating to the sufficiency and accuracy of the data on which these two experts rely. *See, e.g., Sw. Insulation, Inc. v. Gen. Insulation Co.*, No. 4:15-CV-00601-O, 2016 WL 9245433, at *2 (N.D. Tex. Aug. 31, 2016) (holding communications between a non-lawyer and the party's testifying witness were discoverable even when the party's counsel was present for the communication); *Benson v. Rosenthal*, No. 15-782, 2016 WL 1046126, at *6 (E.D. La. Mar. 16, 2016)("[C]ommunications between a testifying expert and a non-attorney are not protected from discovery . . . and must be produced"); *Whole Womens' Health v. Lakey*, 301 F.R.D. 266, 271 (W.D. Tex. 2014)(holding that communications between expert and non-attorney witnesses were discoverable "in order . . . to adequately assess the reliability of [her] opinions").

Moreover, communications between the Government's experts and non-patient witnesses – including communications between the experts – are material to Defendants' ability to challenge the bases (and thus admissibility) of their expected testimony. One example of these types of communications are those that likely exist between Dr. ElSohly and the Gurley Team relating to the four (and maybe more) studies relating to OEP NF that Dr. ElSohly's team conducted ***before*** the Gurley Team's mouse study (with different results). Those studies include:

- **October 2013**: Dr. ElSohly's lab conducted a study that showed that a prior version of OEP (containing DMAA instead of aegeline) was safe at doses higher than the human equivalent of 3 capsules per day (which is itself within the range of the recommended dose on the product's labeling). *See, e.g.*, DOJ_ID00774509 (Ex. 4).

- **November 2013**: Dr. ElSohly's lab conducted a study testing OEP NF on both healthy and health-compromised mice, which showed that OEP NF was not hepatotoxic at doses higher than the human equivalent of 3 capsules per day. *See, e.g.*, DOJ_ID00772978 (Ex. 5); GOV-01473074 (Ex. 6).

- **Sometime in 2013**: Dr. ElSohly's lab conducted a study of the drug interaction potential of aegeline and OEP on certain liver enzymes, which showed aegeline and OEP to be weak inhibitors of certain liver enzymes important to hepatic functioning. *See, e.g.*, DOJ_ID00775968 (Ex. 7).

- **February-April 2016**: Dr. ElSohly's lab conducted a study that appears to have shown that the combination of aegeline and caffeine was safe at human-equivalent levels in excess of the recommended dosages of OEP NF. *See, e.g.*, DOJ_ID00772369 (Ex. 8).

Following its completion of the last of these studies, Dr. ElSohly's lab at the University of Mississippi analyzed and provided to the Gurley Team the OEP NF samples that the Gurley Team used in their 2016 animal study. Gov't Notice, at 35.[8]

It therefore strains credulity that additional communications between Professor Gurley and his team and Dr. ElSohly do not exist. Any communications between or among the Government's experts relating to the Gurley Team's mouse study or Dr. ElSohly's lab's prior

[8] The Government has acknowledged that Dr. Bonkovsky communicated with the Gurley Team. *See* Gov't Notice, at 13.

studies, and any other communications between or among any of the Government's proposed experts, are material to the Defendants' defenses at trial and critical to the pre-trial assessment of the admissibility of the proposed experts' testimony. This material is discoverable under Rule 16 and should be produced well in advance of the *Daubert* hearing. *See Lakey*, 301 F.R.D. at 271.

Third, the Government's proposed experts' prior testimony and expert reports are also material to Defendants' *Daubert* challenges. This type of discovery is commonplace even in civil cases, in order to assess the consistency of experts' views and conclusions over time. For example, Dr. ElSohly's prior testimony in *Sparling v. Doyle*, No. EP-13-CV-323-DCG, 2015 WL 4528759 (W.D. Tex. July 27, 2015), differed significantly from his expected testimony in this case, likely as a result of newly revealed evidence relating to his manipulations of the limit of detection in his DMAA-related research. Such differences in the Government's proposed experts' positions over time are material because they shed light on the unreliability of the current proposed testimony. *See, e.g.*, *Jefferson v. Delphi Auto. Sys. LLC*, No. 2:14-CV-320, 2015 WL 8479066, at *3 (S.D. Tex. Dec. 10, 2015); *Duarte v. St. Paul Fire & Marine Ins. Co.*, No. EP-14-CV-305-KC, 2015 WL 7709433, at *7 (W.D. Tex. Sept. 25, 2015).[9]

Fourth, the Government's proposed experts' workpapers are material to the defense because they provide evidence of the underlying methodology of the experts' testimony, and of the information and data that the experts did – or did not – consider. *See, e.g., Fid. Nat'l Title*

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[9] *See also Medrano v. Sunbeam Prods., Inc.*, No. SA-08-CA-591-XR, 2009 WL 10674189, at *2 (W.D. Tex. Oct. 9, 2009) (explaining that "at times a party can be required to disclose other information about a testifying expert," and citing to *Expeditors Int'l of Washington, Inc. v. Vastera, Inc,* No. 04 C 0321, 2004 WL 406999, at *2 (N.D. Ill. Feb. 26, 2004)), which held discoverable an expert's prior deposition testimony, trial testimony, and expert reports); *In re Enron Corp. Sec., Derivative & ERISA Litig.*, No. CIV.A. H-01-3624, 2009 WL 3247432, at *1 (S.D. Tex. Sept. 29, 2009) ("[A]n expert's report is relevant because bias is of course one of the quintessential bases for impeachment of a witness and [the opposing party] is entitled to inquire into an expert's comparative record in testifying for plaintiffs or for defendants as such. A party is entitled to explore potential inconsistencies between the views [the expert] intends to express in the underlying case, and the testimony and opinions he has given, and the damages theories and methodologies he had adopted in prior cases or on related subjects.") (internal citations and quotation marks omitted) (second alteration in original).

Ins. Co. of N.Y. v. Intercounty Nat'l Title Ins. Co., 412 F.3d 745, 750–51 (7th Cir. 2005) (finding that testifying expert's notes from interviews he conducted with a party's employees were subject to discovery); *SEC v. Reyes,* No. C 06-04435 CRB, 2007 WL 963422, at *1 (N.D. Cal. Mar. 30, 2007) ("When experts serve as testifying witnesses, the discovery rules generally require the materials reviewed ***or generated by them*** to be disclosed. . . ." (emphasis added)).

2. The Requested Expert-Specific Documents Are Material To Preparing Defendants' Defense.

Defendants are also entitled to each category of documents specific to each of the proposed experts identified above, because those documents also inform the reliability of the proposed experts' expected testimony. In the case of Count 10 (the adulteration count), this expected testimony will be the core of the Government's case. These materials are therefore material to Defendants' defenses under Rule 16 and the Court's assessment of each expert's reliability under *Daubert*, and should therefore be produced in advance of the *Daubert* hearing.

a. The Documents Requested By Defendants Relating To Dr. Bonkovsky Are Material To Their Defense Against Count 10.

The requested documents relating to Dr. Bonkovsky are material to Defendants' defense and necessary for an effective pre-trial cross-examination of him at the *Daubert* hearing, for the following reasons:

First, communications between Dr. Bonkovsky and his fellow members of the DILIN network regarding USPlabs, OEP NF, and any ingredient of OEP NF, would likely provide evidence material to Defendants' contention that the DILIN-authored article on which Dr. Bonkovsky relies, *Severe Acute Hepatocellular Injury Attributed to OxyElite Pro* ("Heidemann

Article"),[10] was based on inaccurate and inadequate information from the treating physicians, thus rendering any related testimony unreliable. *See* Bonkovsky Mot. at 4, Dkt # 254-2; *see also* Defs.' Notice Of Expert Test. at 50-55, Dkt # 232. Specifically, because the Heidemann Article was based on assessments by a number of DILIN-affiliated hepatologists, including both the Article's DILIN-affiliated authors and other DILIN hepatologists that provided their own assessments of certain patients behind the scenes,[11] any communications between Dr. Bonkovsky and these other hepatologists would be important to allow the Court to assess whether his reliance on the Heidemann Article was a reliable methodology. Additionally, given DILIN members' publicly expressed skepticism regarding the dietary supplement industry generally,[12] any such communications could expose bias on the part of Dr. Bonkovsky, which could also bear on the admissibility of his testimony under *Daubert*. *See Sw. Insulation, Inc.*, 2016 WL 9245433, at *2(holding discoverable communications between a non-lawyer and the party's testifying witness); *Benson*, 2016 WL 1046126, at *6("[C]ommunications between a testifying expert and a non-attorney are not protected from discovery . . . and must be produced"); *see also United States v. Abel*, 469 U.S. 45, 52 (1984) ("Proof of bias is almost always relevant").

Second, documents relating to Dr. Bonkovsky's January 19, 2016 appearance on PBS's "Frontline," or any other similar statements he has made to the media regarding USPlabs or its

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[10] *See* Bonkovsky Mot., Ex. 13, Dkt # 257-13, (Lauren Heidemann, *et al*., *Severe Acute Hepatocellular Injury Attributed to OxyElite Pro*, 61(9) DIG. DIS. AND SCI. 2741-48 (2016)); *see also* Abstract of a Poster: *Severe Acute Hepatocellular Injury Attributed to OxyElite Pro: Observations from the DILIN Network*; NIH-AASLD Workshop, NIH, Bethesda, MD, May 4-5, 2015 (collectively, "the Heidemann Article").

[11] *See*, *e.g.*, Ex. 9 (patient assessments by DILIN members Bob Fontana, Raj Vuppalanchi, and Jose Serrano, who contributed to the Heidemann Article).

[12] *See, e.g.*, Anahad O'Connor, *Spike in Harm to Liver Is Tied to Dietary Aids*, N.Y. TIMES (DEC. 21, 2013), http://www.nytimes.com/2013/12/22/us/spike-in-harm-to-liver-is-tied-to-dietary-aids.html ("It's really the Wild West," said Dr. Herbert L. Bonkovsky . . . . "When people buy these dietary supplements, it's anybody's guess as to what they're getting.").

dietary supplements, is material to Defendants' challenge to the admissibility of his testimony because those documents will likely show either (1) a methodology of analyzing OEP NF's safety that is inconsistent with the methodology underlying his expected testimony in this case, or (2) a lack of ***any*** scientific investigation into the safety of these supplements at the time he made those statements. Either of these would suggest a willingness on his part to render scientific conclusions based on insufficient data or analysis. *See, e.g.*, *In re Enron Corp. Sec., Derivative & ERISA Litig.*, 2009 WL 3247432, at *1 (S.D. Tex. Sept. 29, 2009) ("A party is entitled to explore potential inconsistencies between the views [the expert] intends to express in the underlying case, and the . . . opinions he has given . . . on related subjects." (internal citations and quotation marks omitted, alteration in original)); *Hussey v. State Farm Lloyds Ins. Co.,* 216 F.R.D. 591, 596 (E.D. Tex. 2003).

Third, communications between (a) Dr. Bonkovsky and any of the employees of the University of Mississippi involved in the testing of aegeline and OEP NF, and (b) communications between members of Phytochemical Services, Inc.,[13] relating to the testing of OEP or any OEP ingredients, are plainly material to whether Dr. Bonkovsky's testimony is sufficiently reliable under *Daubert*. Such communications, which would likely relate to the results of studies testing the safety of aegeline-containing products, could further reveal additional unreliability as to Dr. Bonkovsky's "perhaps" opinion regarding why OEP NF likely caused the liver injuries at issue. *Accord Lakey*, 301 F.R.D. at 271.

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[13] Phytochemical Services, Inc. ("PSI") is a privately held corporation owned by Mahmoud ElSohly, another Government expert that, *inter alia*, analyzes dietary supplements. *See* PHYTOCHEMICAL SERVICES, INC., http://www.phytochemserv.com/ (last visited Oct. 3, 2017); Gov't Notice at 14 (designating Mahmoud ElSohly as a Government expert). In 2014, Dr. Bonkovsky contacted Dr. Khan, an associate of Dr. ElSohly, and asked if Dr. Khan's team could perform an analysis of OxyElite Pro. Dr. Khan subsequently referred Dr. Bonkovsky to Dr. ElSohly, who agreed to conduct the analysis. *See* Ex. 10 (October-November 2014 email exchange between Drs. Bonkovsky, Khan, and ElSohly).

Because these documents are material under Rule 16, potentially exculpatory under *Brady* and *Giglio*, and important to the pre-trial *Daubert* assessment of Bonkovsky's testimony, they should be produced well in advance of the *Daubert* hearing.

b. The Documents Requested By Defendants Relating To Dr. Klontz Are Material To Their Defense.

As discussed in more detail below, the requested discovery relating to Dr. Klontz is also material to Defendants' defense against Count 10 (alleging adulteration), and is critical for a pre-trial assessment of the reliability of Dr. Klontz's methodology.

First, Dr. Klontz submitted articles relating to OEP NF to the *New England Journal of Medicine*, the *American Journal of Preventative Medicine*, and the *Journal of the American Medical Association*. After the peer review process, ***each of these journals refused to publish Dr. Klontz's work***. Documents relating to these journal submissions are therefore material to demonstrating the unreliability of Dr. Klontz's work, as they would show the criticisms that Dr. Klontz's peers had of his research. Communications between Dr. Klontz and these journals are highly likely to highlight the weaknesses in and unreliability of Dr. Klontz's analysis as identified by his peers affiliated with these publications, one of the core *Daubert* factors governing expert admissibility. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594 (1993) ("The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.").

Second, communications between and among Dr. Klontz and his "skeletal crew" (*see* Ex. 11), and documents relating to the 45 medical records that Dr. Klontz told the New Zealand government he reviewed, are likely to provide evidence showing the absence of factual or methodological support for Dr. Klontz's opinion. For instance, in the Government's Notice, Dr.

Klontz claims that he based his conclusions on a review of patient medical records, but fails to identify the medical records upon which he relies.[14]

Third, communications with Paul Howard at the National Toxicology Program are material to Defendants' contention that both OEP and aegeline are safe ingredients. In a document already produced by the Government, Dr. Klontz discussed with another FDA colleague the possibility of getting Dr. Howard involved to conduct animal testing of OEP NF. *See* Ex. 13 (GOV-01550424). Although it is unclear whether Dr. Howard ultimately conducted this testing (the Government has not produced any test results), any communications with him regarding the testing of OEP NF – whether that testing was either only contemplated or actually performed – would likely reveal information shared with Dr. Klontz that would bear on the reliability of Dr. Klontz's methodology. *Accord Lakey*, 301 F.R.D. at 271. Indeed, documents relating to ***any*** testing done by Dr. Howard, even if not communicated to Dr. Klontz, are independently material to Defendants' defense and should also be produced under Rule 16.

Fourth, communications between Dr. Klontz and members of DILIN, many of whom reviewed the same patient files reviewed by Dr. Klontz, are likely to provide evidence of deliberations regarding those diagnoses that forms the basis of Dr. Klontz's expected testimony and conclusions. Thus, these communications are likely to provide evidence important to Dr. Klontz's cross-examination, and thus material to defending against Count 10.

Fifth, communications between Dr. Klontz and employees, members, or affiliates of the Centers for Disease Control and Prevention, the Department of Defense, the University of North Carolina, or Duke University regarding any contemplated testing of blood samples from

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[14] Although the Government has informed Defendants that the patient files reviewed by Drs. Bonkovsky and Klontz are among the 47 patients' files that the Government produced on May 1, 2017, it has refused to identify which specific patient files Dr. Klontz reviewed. *See* Ex. 12 (May 24, 2017 email from Patrick Runkle to Patrick Linehan).

individuals who claimed they experienced hepatitis following OEP NF use, and the identification of control subjects,[15] are likely to provide further evidence that Dr. Klontz's conclusion of a link between OEP NF and liver injury is the result of an unreliable methodology. Dr. Klontz's failure to complete such blood testing would be highly relevant to Defendants' contention that the Government failed to rule out obvious alternative causes of liver injury, an important *Daubert* inquiry. Conversely, if Dr. Klontz did conduct blood testing, these communications will provide evidence of the degree to which alternative causes of liver injury, such as hepatitis, are likely to be the true cause of patients' liver injuries. These documents are therefore material and important to a pre-trial assessment of Dr. Klontz's reliability.

All of these documents are material under Rule 16, potentially *Brady/Giglio* material, and material to the pre-trial determination of whether these experts' expected testimony is admissible. As such, they should be produced well in advance of the *Daubert* hearing.

c. The Documents Requested By Defendants Relating To The Gurley Team.

The documents requested by Defendants relating to Professors Gurley, Koturbash, and Boerma's muse study are also material to Defendants' defense against Count 10 and the reliability of their methodology under *Daubert*, for at least two reasons.

First, documents relating to the professors' prior experience, and the specific instruments, methods, and test animals used in the professors' studies are material to Defendants' challenge that the professors are not qualified in the areas in which they are expected to testify. Such documents could potentially show that their research failed to use methodologies that are reliable or even applicable to the question they hoped to answer.

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[15] *See* Ex. 14 (March 2014 email exchange between Dr. Fabricant at the FDA and Dr. Klontz regarding work with the Department of Defense, the University of North Carolina, and Duke University).

Second, literature the Government believes supports the professors' unvalidated and unscientific method of approximating the relevance to humans of mouse-based liver studies, and literature suggesting that such studies can be reliable even where they lack (a) any positive control group consisting of a known hepatotoxin and (b) groups of mice being administered individual ingredients to determine whether the ingredients exhibit any cumulative effects, are material to the reliability of the professors' study because they may show that the entire predicate of their study – the appropriateness of the dosage given to the mouse subjects – lacks scientific foundation. *See Cellular Commc'ns Equip., LLC v. Apple Inc.,* No. 6:14-CV-251, 2016 WL 6884660, at *1 (E.D. Tex. Sept. 2, 2016) ("[D]ocuments and information disclosed to a testifying expert in connection with his testimony are discoverable by the opposing party, whether or not the expert relies on the documents and information in preparing his report" (citation omitted)); *Estate of Manship v. United States*, No. 04-C-91-M2, 2008 WL 11351590, at *3 (M.D. La. Mar. 10, 2008); *TV-3, Inc. v. Royal Ins. Co. of Am.*, 194 F.R.D. 585, 589 (S.D. Miss. 2000) (holding discoverable all materials provided to an expert, including attorney work product); *Culbertson v. Shelter Mut. Ins. Co.*, No. 97-1609, 1999 WL 109566, at *1 (E.D. La. Mar. 2, 1999) (same).

Because these documents are material under Rule 16, potentially *Brady/Giglio* material, and critical to the pre-trial determination of whether these experts' expected testimony is admissible, they should therefore be produced well in advance of the *Daubert* hearing.

d. The Documents Requested By Defendants Relating To Dr. ElSohly Are Material To Their Defense.

The requested documents relating to Dr. ElSohly are material to the admissibility of Dr. ElSohly's testimony and the defense against the wire fraud counts, and thus should be produced in advance of the *Daubert* hearing.

First, chain of custody documents for the samples tested by Dr. ElSohly and/or provided to Professors Gurley, Koturbash, and Boerma for use in the animal study are relevant to verifying that the samples tested by Dr. ElSohly were, in fact, geraniums, and to verify that the samples were not altered in any way. *See United States v. Messineo*, No. CRIM. A. No. 90-159, 1990 WL 109424, at *2-3 (E.D. La. July 20, 1990), *aff'd*, 943 F.2d 1313 (5th Cir. 1991) (requiring production of chain of custody documents under Rule 16); *Flynn v. State Farm Fire & Cas. Ins. Co. (Texas)*, No. EP-08-CV-305-PRM-(RPM), 2009 WL 10669696, at *4 (W.D. Tex. May 12, 2009) (granting motion to compel discovery for chain of custody documents); *see also Christian v. Frank*, No. 04-CV-743, 2015 WL 1307303, at *4 (D. Haw. Mar. 24, 2015) (same).

Second, communications between Dr. ElSohly and his team relating to his DMAA-related work are critical to establishing the inadmissibility of Dr. ElSohly's testimony, as they could further confirm that (1) Dr. ElSohly's purported limit of detection is not rooted in a reliable scientific methodology, (2) his research was substantially biased by his goal of *not finding* DMAA in geraniums and from pressure by U.S. Anti-Doping Agency ("USADA"),[16] and (3) he, in fact, detected DMAA in geraniums, but later concealed his detection by manipulating the limit of detection in his research.

Third, communications between Dr. ElSohly and Dr. Armstrong are also critical to corroborating the unreliability of Dr. ElSohly's research. Dr. Armstrong is an analytical chemist whose research, like Dr. ElSohly's research, was directed by the FDA, and was evidently also altered to show the absence of DMAA in geranium at around the same time as Dr. ElSohly's research. Specifically, on May 23, 2012, Amy Eichner, from USADA, emailed Dr. ElSohly an embargoed prepublication copy of Dr. Armstrong's study, which stated, "Trace amounts of

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[16] ElSohly Mot. at 3-14.

DMAA were detected in only two geranium products." [17] Two days prior to the embargoed paper's publication, the publication was postponed because of a "typo."[18] When the article was eventually published, the primary finding of the study – that DMAA was detected in geranium – had been eliminated, replaced by the following phrase: "No DMAA was detected in any of the eight geranium products with a limit of detection of 10 parts per billion (w/w)."[19] Any communications between Dr. Armstrong and Dr. ElSohly could therefore provide additional evidence relating to Dr. ElSohly's contrived and unsubstantiated 10 ppb limit of detection, and may also provide admissible evidence regarding Dr. Armstrong's identification of DMAA in geraniums notwithstanding his reported conclusions to the contrary.

Fourth, communications between Dr. ElSohly and Dr. Yi Jin, Xu Xishuangbanna, Jinghua Yang, Wei-Dong Zhang, Juan Su, Dean Guo, or Min Yang are material to Defendants' defense that DMAA is a natural constituent of geraniums. Specifically, communications between Dr. ElSohly and Dr. Yi Jin, the individual who collected geranium samples for both Dr. ElSohly and for Defendants' expert Dr. Simone, are material to whether Dr. ElSohly attempted to acquire geranium samples from the same regions that ultimately were found to contain DMAA. *See* ElSohly Mot. to Exclude at 18. Dr. ElSohly's communications with the other individuals listed above, all of whom worked with Dr. ElSohly in his Multi-Center Study,[20] are

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[17] *See* Ex. 15 (email from Amy Eichner at USADA to Dr. ElSohly forwarding an embargoed pre-publication copy of an article by Dr. Armstrong identifying DMAA in geraniums).

[18] E. Watson, "USPlabs promises new data that 'definitively' proves presence of DMAA in geranium," *NUTRA Ingredient* (July 16, 2012), *available at* http://www.nutraingredients-usa.com/Research/USPLabs-promises-new-data-that-definitively-proves-presence-of-DMAA-in-geranium ("[W]hile the original version had indeed said that DMAA had been detected in two geranium oils samples of the level of less than 10ppm, the correct figure was in fact at the 10s of parts per billion (ppb), [Dr. Amstrong] said."); Physical Science News (Wiley), "Stimulant Marketed as 'Natural' in Sports Supplement Actually of Synthetic Origin" (May 2012).

[19] *See* Ying Zhang *et al.*, *1,3-Dimethylamylamine (DMAA) in supplements and geranium products: natural or synthetic?* 4 DRUG TESTING ANALYSIS 986 (2012) ("Zhang Study"); Gov't Notice, Ex. 4 at 6-10, Dkt # 222-4.

[20] Mahmoud A. ElSohly et al., *Methylhexanamine is not detectable in Pelargonium or Geranium species and their essential oils: A multi-centre investigation*, DRUG TEST. & ANALYSIS 9 (2014) ("Multi-Center Study"); Gov't Notice, Ex. 3 (Multi-Center Study), Dkt #222-3.

material to showing that Dr. ElSohly's 10 ppb detection limit was not rooted in reliable scientific methods, and the extent to which Dr. ElSohly pressured other labs in the Multi-Center Study to avoid detection of DMAA in geraniums. *See, e.g.*, *id.* at 12-14; *accord Lakey*, 301 F.R.D. at 271.

For these reasons, the requested documents relating to Dr. ElSohly are material under Rule 16, potentially *Brady/Giglio* material, and critical to his pre-trial cross-examination. They should therefore be produced well in advance of the *Daubert* hearing.

e. The Documents Requested By Defendants Relating To Oberlies Are Material To Their Defense.

The documents requested by Defendants relating to Oberlies are material to their defense and for the exclusion of Oberlies' testimony, and must be produced in advance of the *Daubert* hearing for the following reasons:

First, documents relating to Oberlies' research on DMAA's chirality are material to Defendants' contention, as discussed in their Motion to Exclude Oberlies' Testimony, that many molecules found in natural products occur in nature as racemic mixtures, and that the ratio of stereoisomers for some ingredients varies depending on where the plant is grown. *See* Oberlies Mot. at 15, Dkt 252. Thus, they are material to rebutting the Government's contention that DMAA did not qualify as a legal dietary ingredient.

Second, studies that Oberlies reviewed regarding the natural and synthetic compositions of DMAA, aegeline, and Yohimbine, and *Cynanchum Auriculatum* are material to whether the synthetic versions of these ingredients are materially identical to their naturally-occurring counterparts, and are thus legal dietary ingredients under the law and the FDA's rules and regulations. Moreover, these studies would be material to demonstrating that (1) Oberlies has no basis to suggest that synthetic versions of these botanicals pose any greater safety risk than their naturally sourced counterparts, (2) the Yohimbe bark extract used in Defendants' products is an

extract, and not, as Oberlies contends, a synthetic bioequivalent to naturally occurring Yohimbine, and (3) Oberlies' opinion regarding the safety and properties of *Cynanchum Auriculatum* are not reliable. *See* ElSohly Mot. at 25.

Third, documents and notes related to Oberlies' testing of DMAA, aegeline, Yohimbe bark extract, and *Cynanchum Auriculatum* are material to assessing the reliability of Professor Oberlies' methodology.

Fourth, documents relating to Oberlies' research on aegeline are material to evaluating whether his conclusions regarding the stereoisomer ratio of naturally occurring aegeline are reliable, or is instead is based only on his own *ipse dixit*. For instance, these documents could show whether Oberlies was able determine the stereoisomer ratio of naturally occurring aegeline, or whether any pharmacological difference exists between aegeline's R- and S- configurations. Similarly, documents relating to Oberlies' own research on the chirality of Yohimbine, and alleged differences between synthetic and naturally produced Yohimbine, are material to demonstrating that the Yohimbe extract contained in OEP NF is not synthetic as Oberlies concludes, and that his opinion that there is a difference between Yohimbine and a synthetic bioequivalent is unreliable.

Fifth, documents related to Oberlies' research on *Cynanchum Auriculatum* are material to whether the aqueous extract of Cynanchum root contained in OEP NF caused the supplement to be adulterated.

Because the requested documents relating to Oberlies are material under Rule 16, potentially *Brady/Giglio* material, and critical to his pre-trial cross-examination, they should therefore be produced well in advance of the *Daubert* hearing.

f. The Documents Requested By Defendants Relating To Ms. Tucker Are Material To Their Defense.

Lastly, Ms. Tucker's workpapers are material to Defendants' defense and necessary to a full assessment of her admissibility as an expert witness under *Daubert*, because they are likely to provide evidence that Ms. Tucker did not employ a reliable methodology, and moreover, that she failed to examine data necessary to support the conclusions about which she is expected to testify. Specifically, Ms. Tucker's workpapers are material to determining whether the charts that she compiled in support of her testimony[21] accurately reflect the transactions they purport to record, and whether they offer a sufficient factual basis for her testimony. *See Fid. Nat'l Title Ins. Co. of N.Y.,* 412 F.3d at 750–51; *SEC v. Reyes,* 2007 WL 963422, at *1. These documents are material under Rule 16, potentially *Brady/Giglio* material, and critical to her pre-trial cross-examination, and should therefore be produced well in advance of the *Daubert* hearing.

B. Documents In the Possession Of The Government's Proposed Experts Are Within The Government's "Control" Under Rule 16.

The Government should produce in advance of the *Daubert* hearing not only those requested documents that are physically in the Government's possession, but also those documents that are in the possession, custody or control, of its proposed experts, as those documents are nonetheless within the "control" of the Government under Rule 16(a)(1)(E).

When the Government retained its proposed experts, it gained access and control over the proposed expert's relevant documents. "The discovery rules are not so stilted as to provide that the [G]overnment's expert witnesses are not within the control of the [G]overnment." *See United States v. Liquid Sugars, Inc.*, 158 F.R.D. 466, 474–75 (E.D. Cal. 1994). As applied here, the documents requested by Defendants are either already in the possession of the Government, or in the possession of the Government's experts, and therefore within the control of the Government. Indeed, in *United States v. JB Tax Prof'l Servs., Inc.*, No. CRIM.A. 13-127, 2014

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[21] Gov't Notice, Ex. 16.

WL 2533773, at *2 (E.D. La. June 5, 2014), the Court held that the Government must produce not only materials in its experts' possession that "the prosecutor has actually reviewed," but also those documents "to which the prosecutor has knowledge of and access to..." *Id.* (citation and internal quotation marks omitted). Thus, the Government is obligated to produce the requested documents, whether in its possession or its experts.[22]

C. The Requested Documents Must Be Produced Well In Advance Of The Upcoming *Daubert* Hearing.

The documents requested by Defendants' must be produced well in advance of the *Daubert* hearing because they are material to both Defendants' defense and the Defendants' cross-examination of the Government's experts at the *Daubert* hearing. *See Diakhoumpa*, 171 F. Supp. 3d at 151 (holding that the Government must disclose expert witness documents that are "material to [Defendants'] defense and meaningful to [the defendant's] cross-examination [of the Government's expert]"); *see also* Fed. R. Evid. 705 adv. comm. notes (1993 amendment). Indeed, the advisory committee notes to Rule 705 make clear that under Rule 16, "[i]f a serious question is raised under Rule 702 or 703 as to the admissibility of expert testimony, disclosure of the underlying facts or data on which opinions are based may, of course, be needed by the court ***before deciding*** whether, and to what extent, the person should be allowed to testify." *Id.* (emphasis added). Because Rule 705 clearly contemplates the production of expert discovery before the court's decision regarding the admissibility of expert testimony, the Government

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[22] The Government has likely reviewed many if not all of the general expert documents requested by Defendants. For instance, the Government surely has engagement letters for and invoices from each expert. It is hard to imagine that the Government, in selecting its proposed experts, did not also review those proposed experts' prior expert reports, deposition transcripts, and hearing transcripts. Moreover, the Government has supposedly reviewed materials in complying with the court's order to identify all potentially exculpatory documents in accordance with its *Brady/Giglio* obligations. *See* Ex. 16 (letter from P. Runkle to C. Weiland identifying expert documents among *Brady/Giglio* material).

should be required to produce all relevant expert discovery well in advance of the upcoming *Daubert* hearing.

III. CONCLUSION

For the reasons set forth herein, the Court should grant Defendants' Joint Motion To Compel Expert Materials.

Respectfully submitted:

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CERTIFICATE OF CONFERENCE

On October 20, 2017, Mike Gibson, Counsel for Defendant Geisler, conferred with Counsel for the Government regarding the relief requested in this Motion. The Government disagrees with the relief requested in this Motion, so the Motion is therefore opposed.

/s/ Richard B. Roper
Richard B. Roper

CERTIFICATE OF SERVICE

On October 30, 2017, I electronically submitted the foregoing document with the clerk of the court of the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served the U.S. Probation Officer, all counsel of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2), and the probation officer assigned to the case.

/s/ Richard B. Roper
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